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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	12 Civ. 3479 (SAS) (FM)
RICHARD HART and MARIE LOUISE TRUDEL-HART, Plaintiffs, v. SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Defendants.	12 Civ. 3560 (SAS) (FM)

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION *IN LIMINE* TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF CARRIE M. KUEHN

Defendants Richard Hart and Marie Louise Trudel-Hart (the "Harts") respectfully submit this Reply in support of their motion in limine to exclude the expert report and testimony of Carrie M. Kuehn pursuant to Federal Rule of Evidence 702.

PRELIMINARY STATEMENT

The Harts' motion *in limine* showed that Plaintiffs' United States Food and Drug Administration ("FDA") expert, Carrie M. Kuehn, is not qualified to opine about American Diagnostica, Inc.'s ("ADI") compliance with the Quality Systems Regulations ("QSRs") between January 1, 2006 and April 20, 2009. To stave off disqualification, Plaintiffs make three arguments: (1) the Harts ignored Ms. Kuehn's purported "eighteen years of experience"; (2) the Harts ignored Ms. Kuehn's joint authorship of a chapter in a trade manual regarding premarket submissions for medical devices; and (3) the Harts' failed to give credence to Ms. Kuehn's receipt of a Regulatory Affairs Certificate ("RAC") in 2011. Plaintiffs' Opp. to Defendants' Motion *In Limine*, Dkt. 80, at 6-7. None of Plaintiffs' arguments establish Ms. Kuehn's expertise.

First, Ms. Kuehn does not have eighteen years of qualifying QSR experience. She has zero. Ms. Kuehn is an epidemiologist by training and, prior to joining Exponent in 2008, all of her experience was in that field. After joining Exponent, Ms. Kuehn continued to work in the field of epidemiology. *See* Expert Report of Carrie M. Kuehn, Oct. 18, 2013, attached as Exh. 1 to Briley Decl., App. A at 2 (Ms. Kuehn is a member of Exponent's "Biomedical Engineering practice"); "Medical Devices & Biomedical Engineering," from Exponent website, attached as Exh. 2 to Briley Decl., at 2 (Exponent's scientists offer expertise in, *inter alia*, epidemiology). Ms. Kuehn's only QSR experience is as a litigation consultant for Exponent clients. *See* Exh. 1 to Briley Decl., App. A at 2. As this Court has stated, experience gained as a litigation

consultant or expert witness is not the "knowledge, skill, training, education, or experience" required by Rule 702. *See Pension Comm. of the Univ. of Montreal Pension Plan v. Bank of Am. Secs. LLC*, 716 F. Supp. 2d 220, 225 (S.D.N.Y. 2010) (Scheindlin, J.) (citing *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791 (4th Cir. 1989) (reversing admission of expert testimony because expert's only qualification was serving as expert witness)).

Second, the trade manual chapter Ms. Kuehn co-authored has nothing to do with the QSRs and does not qualify Ms. Kuehn to opine about the QSRs. The chapter is a summary of requirements for premarket submissions for medical devices. *See* "Bringing Your Medical Device to Market," Table of Contents and Preface, attached as Exh. 3 to Briley Decl., App. A at 3-9. The premarket submission requirements are codified separately from the QSRs and enforced by a separate division within the FDA.[1] Expertise in one area does not demonstrate expertise in the other.[2] None of the other sixty-nine publications listed on Ms. Kuehn's *curriculum vitae* have anything to do with QSRs. Those sixty-nine credits are studies of disease prevalence and effects, presentations of data, and analyses of human remains. *See* Exh. 1 to Briley Decl., App. A at 3-9. Ms. Kuehn's writings have nothing to do with the area in which she is proffering her opinion in this case.

[1] Premarket submissions are governed by Part 807 of Subchapter H of the Code of Federal Regulations. *See* 21 C.F.R. §§ 807.81-.100. The QSRs are codified in Part 820 of Subchapter H. *See* 21 C.F.R. § 820 *et seq.* ("Quality System Regulations"). Either the FDA's Office of Device Evaluation or its Office of In Vitro Devices reviews and makes decisions about premarket submissions. *See* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115879.htm; http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115904.htm. The Office of Compliance enforces the QSRs. *See* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115809.htm.

[2] Indeed, Plaintiffs' argument to exclude a portion of the report and testimony of the Harts' expert, Thomas D. Becze, is premised on this distinction. *See* Dkt. 80 at 3.

Third, Ms. Kuehn's receipt of RAC in 2011 does not qualify her as an expert. To receive this certification, Ms. Kuehn only had to pay a fee and pass a 100-question multiple-choice examination. *See* Regulatory Affairs Certification Candidate Guide, attached as Exh. 4 to Briley Decl., at 2. No relevant coursework or work experience is required to take the RAC exam. *Id.* The certification is awarded solely on the basis of the exam. *Id.* No court has ever found RAC to be a "meaningful expert qualification," Dkt. 80, at 6, and no court has ever held that RAC alone qualifies an individual as an expert. If this Court so held, it would be the first.

In addition to her lack of expertise and experience qualifying her as an expert, Ms. Kuehn's opinion is not based on sufficient facts or data. To defend Ms. Kuehn's methodology, Plaintiffs argue that she considered sufficient facts and data because her conclusions were "verif[ied]" by current ADI employees. Dkt. 80 at 8. This argument is without merit. The individual responsible for compliance at ADI during the relevant time period was Leigh Ayres, a former employee of ADI. Ms. Kuehn did not speak with Ms. Ayers or any other employee responsible for compliance during the relevant time period. *See* Exh. 1 to Briley Decl. at 22 n.129 (citing "Personal communication with Sekisui personnel, June 24 and 25, 2013"); 25 n.167 (same); 38 n.298 (same).

Ms. Kuehn also failed to reconcile her document review with the auditing procedures and findings of the regulators and customers who audited ADI from 2005 to 2009, including the FDA. There were seven such audits in the relevant period. Each of these audits included an on-site inspection of the facility and interviews of the ADI managers responsible for drafting and implementing documents of the type Ms. Kuehn reviewed, as well as a review of those documents. All of these audits found that ADI was compliant. Ms. Kuehn considered none of

this other information. Nor could she explain away their unanimous findings that ADI was compliant.

ARGUMENT

To qualify as an expert, a witness must possess "specialized knowledge" that will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. To meet this burden here, a witness must have sufficient experience or expertise to: 1) identify the relevant FDA regulations applicable to medical device manufacturers, 2) explain how the FDA interprets those regulations, and 3) explain how the FDA applies and enforces those regulations. Ms. Kuehn has no qualifying experience or expertise.

I. Ms. Kuehn is Not a Qualified Expert.

A. Ms. Kuehn Does Not Have Eighteen Years of Relevant Training or Experience.

Ms. Kuehn does not have eighteen years of experience in FDA regulatory affairs, quality assurance, or the QSRs. She has zero. Ms. Kuehn is "[a]n epidemiologist by training." Exh. 1 to Briley Decl. at 2. From 1998 to 2008, Ms. Kuehn worked as an epidemiologist and forensic autopsy technician. *Id.* In 2008, Ms. Kuehn joined Exponent. *Id.* It appears from her *curriculum vitae* that Ms. Kuehn has continued to work in the field of epidemiology since joining Exponent. *See* Exh. 1 to Briley Decl., App. A at 3 (publications regarding epidemiology in 2010 and 2013). Ms. Kuehn's *curriculum vitae* states that, after joining Exponent, she did eventually gain some experience with QSRs, but only as a litigation consultant. *See id.* (Ms. Kuehn provides "consulting expertise in medical device regulatory affairs and QSR documentation to support medical device related litigation"). This does not qualify her. Indeed, this Court has said that "courts are generally wary of [] experience gained as a litigation consultant and expert witness." *Pension Comm.*, 716 F. Supp. 2d at 225.

Ms. Kuehn has no relevant non-litigation experience. Plaintiffs claim that Ms. Kuehn has counseled companies seeking to establish quality systems or that have been inspected by the FDA. *See* Dkt. 80 at 5. For support, Plaintiffs cite Ms. Kuehn's *curriculum vitae* and deposition transcript, neither of which makes any such statements.[3] *See id.* All of Ms. Kuehn's non-litigation-related experience is assisting with the preparation of premarket submissions and analyzing data about marketed medical devices. *See* Exh. 1 to Briley Decl., App. A at 2. (Ms. Kuehn provides "strategic and technical support for pre- and post-market medical device safety issues, regulatory pathway determination, and FDA submission[, and] analysis of post-market medical device surveillance data"). None of this experience has anything to do with the QSRs, which is the only issue on which Ms. Kuehn opines in this case.

Further, Ms. Kuehn has never worked at the FDA. Plaintiffs moved to exclude certain testimony of the Harts' FDA expert, Thomas D. Becze, because Mr. Becze has never worked at the FDA. *See* Plaintiffs' September 16, 2013 Letter to the Court, Dkt. 53, at 6; Plaintiffs' Motion *in Limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze, Dkt. 65, at 3 (Mr. Becze not qualified to opine on Femtelle 510(k) because "he has never worked at the FDA"). Plaintiffs now backpedal on this argument. Dkt. 80 at 2. Whether or not FDA experience is a necessary qualification, it is clear that Ms. Kuehn has no relevant experience to assist the court on the central issue in this case.

[3] Ms. Kuehn's *curriculum vitae* states that she provides "consulting in medical device regulatory affairs and QSR documentation to support medical device related litigation." Exh. 1 to Briley Decl., App. A at 2. Ms. Kuehn testified during her deposition that she has never been employed professionally in connection with an FDA inspection. *See* Transcript of Aug. 22, 2013 Deposition of Carrie M. Kuehn, attached as Exh. 5 to Briley Decl., at 15:4-25.

B. Ms. Kuehn's Co-Authorship of a Chapter in a Trade Manual Does Not Qualify Her as an Expert.

Plaintiffs argue that Ms. Kuehn's qualifications include that she is "widely published." Dkt. 80 at 3. The Harts do not dispute that Ms. Kuehn is a prolific writer, but her writings are irrelevant to the QSRs and do not qualify her as an expert here. Ms. Kuehn's *curriculum vitae* lists thirty publications and forty presentations. *See* Exh. 1 to Briley Decl., App. A at 3-9. Sixty-nine of these seventy credits concern epidemiology and forensic pathology, in which fields Ms. Kuehn has published numerous studies of disease prevalence and effects, presentations of data, and analyses of human remains. *See id.* All are unrelated to compliance with the QSRs, which is the subject of Ms. Kuehn's testimony. *See id.*

Plaintiffs point to the only remaining publication on Ms. Kuehn's *curriculum vitae* and claim that this publication alone establishes her expertise. Plaintiffs are wrong. The referenced publication is a sixteen-page chapter in a trade manual, "Bringing Your Medical Device to Market," which Ms. Kuehn co-authored. *See* Exh. 3 to Briley Decl. at 4. This chapter is a summary of the FDA requirements for premarket submissions for medical devices, and has nothing to do with the subject on which Plaintiffs seek to submit Ms. Kuehn's testimony. *See id.* at 5-6.

C. Regulatory Affairs Certification Does Not Quality Ms. Kuehn.

Plaintiffs argue that Ms. Kuehn's RAC qualifies her because "courts routinely find that RAC is a meaningful expert qualification" and cite three cases. Dkt. 80 at 6. None of the cases Plaintiffs cite holds—or even comments—that "RAC is a meaningful expert qualification." *See In re Celexa and Lexapro Products Liability Litigation*, 2013 WL 791784 (E.D. Mo. March 4, 2013); *Woodard v. Stryker*, 2012 WL 3475079 (Wyo. July 12, 2012); *Schott v. I-Flow Corporation*, 696 F. Supp. 2d 898 (S.D. Ohio 2010).

Unlike Ms. Kuehn, the experts qualified in these cases all had extensive experience in the areas in which they were opining. *See id.* at *2-*3; *Woodard*, 2012 WL 3475079 at *8-*9; *Schott*, 696 F. Supp. 2d at 904. In each case, the court found the expert to be fully qualified based not on the expert's receipt of RAC but on his or her extensive relevant experience. *See Woodard*, 2012 WL 3475079, at *8 (expert had "over thirty-seven years of experience in the research of pharmaceutical and biotechnology-derived medical devices"); *In re Celexa*, 2013 WL 791784 at *3 (expert had a Ph.D. in pharmacology and "more than 25 years experience in drug, biologic, and medical device regulatory affairs"); *Schott*, 696 F. Supp. 2d at 904 (expert had thirty-five years of experience "working in the field of F.D.A. regulatory issues"). Each expert was also highly respected in the industry. *See id.* (expert had served as authorized representative for FDA matters for medical device and drug companies); *In re Celexa*, 2013 WL 791784 at *4 (expert had published extensively on regulatory issues, taught several university courses, and served as editor-in-chief and an editorial board member of several professional publications).

Although in all three cases the courts mentioned RAC, they did so after listing the expert's extensive qualifications and noting that the expert had been elected a RAPS Fellow. *See id.* at *2; *Woodard*, 2012 WL 3475079 at *8; *Schott*, 696 F. Supp. 2d at 904. Election as a RAPS Fellow is a substantially more significant achievement than receiving RAC. *See* "RAPS Fellows," from RAPS website, attached as Exh. 6 to Briley Decl. Ms. Kuehn is not a RAPS Fellow. To be elected a RAPS Fellow, a professional must be recognized by his or her peers, have at least fifteen years of regulatory experience, and have achieved the highest professional level of skill and experience in the industry, typically Chief Regulatory Officer, Executive Director, or President of a company. *Id.*; *see also* Regulatory Affairs Professional Development Framework, attached as Exh. 7 to Briley Decl., at 15. There are only seventy-nine RAPS

Fellows worldwide. *See* http://www.raps.org/membership-amp-benefits/raps-fellows/past-raps-fellows-inductees.aspx. Ms. Kuehn lacks any qualification for election as a RAPS Fellow.

II. Ms. Kuehn's Opinion is Not Based on Sufficient Facts and Data.

Plaintiffs do not dispute that Ms. Kuehn's methodology consisted solely of reviewing certain documents hand-selected by Plaintiffs for her review. Instead, they argue that this methodology is valid because Ms. Kuehn confirmed her findings by interviewing current ADI employees and that she bases her opinion on defective as well as missing documents. Plaintiffs' arguments are unavailing.

Ms. Kuehn's interviews of current ADI employees are irrelevant. Ms. Kuehn did not interview Leigh Ayres, ADI's Director of Quality Assurance and Regulatory Affairs from 2004 to 2010, or any other ADI employee who had any responsibility for regulatory compliance during the relevant time period. *See* Exh. 1 to Briley Decl. at 22 n.129 (citing "Personal communication with Sekisui personnel, June 24 and 25, 2013") (emphasis added); 25 n.167 (same); 38 n.298 (same). The FDA instructs inspectors to interview management before the start of each inspection to "obtain an overall view of the [company] as well as a feel for management's knowledge and experience." FDA Quality System Inspection Technique, Guide to Inspections of Quality Systems, attached as Exh. 8 to Briley Decl., at 15. Ms. Kuehn rendered her opinion without taking this key step. Ms. Kuehn also failed to consider that, during the relevant period, at least seven on-site audits found ADI compliant.[4] These audits were conducted by regulators and customers, and included interviews of key personnel. *Id.* No audit during the relevant period found ADI noncompliant. Ms. Kuehn does not explain how her analysis can be

[4] The relevant portions of these audits are attached as Exhs. 3-11 to the Declaration of Siobhan Briley, Dkt. 73, submitted in support of the Harts' motion *in limine*.

reconciled with the findings of every other auditor of ADI during the relevant period. *See* Exh. 1 to Briley Decl. at 34-36.

Ms. Kuehn also failed properly to review the documents Plaintiffs did provide to her. The Harts' FDA expert, Thomas D. Becze, identified in his rebuttal report several documents produced by Plaintiffs that directly contradicted Ms. Kuehn's conclusions that ADI was missing documents. *See, e.g.*, Expert report of Thomas D. Becze, attached as Exh. 9 to Briley Decl., App. 3 at 1 (¶2), 8 (¶4), 10 (¶4). After reviewing Mr. Becze's findings, Ms. Kuehn submitted an amended report. *See* Kuehn Memo, Oct. 17, 2013, attached as Exh. 10 to Briley Decl., at 1-2, 2-3, 4.

Finally, Plaintiffs argue that Ms. Kuehn's opinion is not based solely on missing documents but also on documents that are "noncompliant on their face." *See* Dkt. 80 at 9. This is incorrect. Ms. Kuehn bases her opinion on documents that, she says, should have been signed but were not. In other words, Ms. Kuehn opines that because she did not see the final, signed versions of certain documents, ADI was not in compliance. *See, e.g.*, Exh. 1 to Briley Decl. at 13 (Internal Audit Certification Forms (GEN031-2F) and Internal Audit Reports (GEN031-3F) not signed). *id.* at 21 (qualification validation summary and report for lyophilizers not signed); *id.* (Installation Qualification/Operational Qualification/Performance qualification documents not signed); *id.* (maintenance procedures in draft form or not signed); *id.* at 22 ("forms used to record in-process activities and testing of product components" not signed); *id.* at 28 (certain other SOPs were not signed). Had Ms. Kuehn seen final versions of these documents, the earlier, unsigned versions would not have been evidence of noncompliance. Thus, Ms. Kuehn's opinion is premised on her claim that signed originals are missing in the papers provided to her by Plaintiffs.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion in limine to exclude the report and testimony of Carrie M. Kuehn.

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